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Expert View

Diagnostics as the Key to Advances in Global Health: Proposed Methods for Making Reliable Diagnostics Widely Available

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This paper proposes a structure and method for the development of an AI diagnostic system as a highly leveraged step toward improvements in delivery of healthcare in underserved regions. First, the paper provides a high-level, general review of the current efforts to provide healthcare services in underserved areas and the many efforts being made to impact health outcomes by various international, governmental, and NGO entities. We also very briefly review university programs and research institutions that have specific technical and institutional assets with significant potential to carry out research or to partially implement such a plan. Our review uses weighted values in a decision-system that takes in a variety of assets we consider fundamental to successful engagement in delivery of new, innovative, technology-enabled healthcare systems for under-resourced settings. We then review nine factors that hinder the advancement in healthcare in under-resourced settings, some of which are well described in current literature and some that may bring new perspectives. The paper then attempts to review how a proposed system can manage to operate successfully within the context of the nine named hindrance factors. The primary focus of the paper is in the description of a system which can increase the availability of diagnostics through technology-enabled systems. Such a system would impact the outcomes of persons in underserved regions. The paper then describes why making diagnostics available is a critical priority among efforts for improvements in global health. [DOI: 10.1115/1.4046046]

Introduction

Global health has changed significantly in the past three decades. The coordinated efforts of the United Nations member states and multiple international organizations through the Millennium Development Goals (MDG) have yielded remarkable progress. For example, between 1990 and 2015, the global under five mortality rate and maternal mortality rate decreased by 53% and 45%, respectively. Newborn vaccination and contraceptive uptake by women of childbearing age also improved in the same period [1].

Cooperation between international organizations such as the World Bank, World Health Organization (WHO), along with governments, Non-Governmental Organizations (NGOs), and charities was critical in achieving these results [2]. For example, organizations such as the Global Fund to End HIV/AIDS, Tuberculosis, and Malaria contributed to saving millions of lives through the availability of antiretroviral drugs and insecticide-treated bed nets. In addition, global health statistics previously accessible to only public health professionals were simplified and made available to millions of people by organizations like Gapminder and Worldmapper enabling increased participation of the public [3–6].

Despite these achievements, more than half of the world's population still have limited access to essential health services [7].

The Status of Global Health

The primary international agencies working in global health remain the WHO and the World Bank. Their work is supported by many other international agencies such as the United Nation International Children's Emergency Fund (UNICEF), the United Nations Development Program (UNDP), United Nations Women,

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the United Nations High Commissioner for Refugees (UNHCR), all of which are important stakeholders in global health.

Some countries also have nonmultilateral efforts in global health such as the U.S. Agency for International Development (USAID) and the Centers for Disease Control and Prevention (CDC), and Germany's Deutsche Plattform für Globale Gesundheit and International Advisory Board on Global Health.

The number of institutions, NGOs and private charities, engaged in global health are in the hundreds. The engaged parties range from large, reputable humanitarian aid organizations such as Médecins Sans Frontieres (MSF) and the International Federation of the Red Cross and Red Crescent Societies to much smaller and newer organizations. The American Family Physicians Association, for example, lists dozens of international medical relief agencies founded by its members, operating in underserved regions [8,9].

Important research and training programs are also originating from academic institutions around the world. Over 75 specialty training programs across these institutions offer advanced degrees in global health. Using a decision algorithm, these institutions are ranked here to assess their likelihood of participating in future technology-enabled healthcare projects in underserved regions. Weighted scores were generated based on global health research output; evidence of multidisciplinary approaches or international collaborations in global health projects; level of advancement of institution's healthcare information technology infrastructure; biomedical engineering research and intellectual property outputs; and adoption of global health policy statements or related mission statements.

Among these institutions, the highest ranking were: London School of Hygiene & Tropical Medicine; Johns Hopkins University; Stanford University; Harvard University; University of Toronto, and others as shown in Fig. 1.

While viewing the ranking of these top 11 universities, consider that each has unique strengths and expertise that better serve in different situations.

Of the university institutes/programs and NGOs formed to address global health, the work of these parties generally falls into two categories:

(1) Advocacy or strategy efforts in global health;
(2) Efforts specific to disease conditions (e.g., HIV/AIDS, Malaria, etc.) or regions (e.g., Haiti).

Many of the advancements in global health have come down to rather specific interventions such as the broad availability of insecticide-treated bed nets and antiretroviral drugs.

Problems Affecting Global Health Progress Today

The obvious and highest-level problem in addressing global health concerns come down simply to the lack of distribution of healthcare resources across world populations. This results in more than half of the world population being underserved [10]. In the following paragraphs common problems in global health today are described.

Lack of Resources in Poor Countries. A lack of resources is often the result of a combination of the lack of financial resources in national revenues and a low mean per capita income. This lack of resources can also be the result of funds being misdirected by corrupt governments. Transparency International, in its report on the MDGs, shows a direct correlation between the level of corruption in specific regions and its impact on health outcomes [11,12].

Funding Priority Issues. This comes down to choices in national funding priorities that take funds away from healthcare. Except for healthcare spending in the U.S., there is a generally correlated relationship between spending and outcomes (the U.S. data on the relationship between healthcare spending per capita and health outcomes can be considered an outlier). Funding decisions that deprioritize healthcare in favor of noneconomic drivers may have direct relationship to healthcare outcomes [13].

University / Institute Decision System for Global Health Participation in Technology Enabled Diagnostic System:

Weighted Values:

5	a	Multi-disciplinary Global Health approach, integration of multi-disciplinary cooperation in practice
5	b	Relevant / strong IT capabilities, especially around medical records, AI, medical diagnostic systems
4	c	Strength in Medical Device development or Bio-engineering Departments
4	d	Global Health International Activities or Outreach
2	e	Number and Depth of Advanced Degree Programs in Global Health
3	f	Global Health Research
4	g	Strength of Medical School
3	h	Global health Policy Departments, Institutes, Entities ("strategy", "analysis", "think tank"). Institutions having public Global Health Policy Statements, related mission statements, or related public statements

	Scoring Table	Score Solution 0 - 5, 5 being highest score or 100%								Score	%
		a	b	c	d	e	f	g	h		
	Scoring Table										
x	Sample, potential technology, best case	5	5	5	5	5	5	5	5	150	100%
1	London School of Hygiene & Tropical Medicine	5	5	5	5	5	5	5	5	150	100%
2	Johns Hopkins University	5	5	3	5	5	5	5	5	142	95%
3	Stanford University	5	5	5	4	4	4	5	4	138	92%
4	Harvard University	4	5	5	5	5	4	5	3	136	91%
5	University of Toronto	5	3	4	5	5	5	4	5	132	88%
6	University of Minnesota	4	5	5	3	4	4	5	3	126	84%
7	Barcelona Institute for Global Health	5	5	2	5	4	4	3	5	125	83%
8	University of California, San Francisco	4	4	3	5	4	4	4	4	120	80%
9	Tufts University	4	4	3	5	3	4	4	4	118	79%
10	University of Maryland, Baltimore	4	3	3	4	3	4	4	4	109	73%
11	University of California, San Diego	3	2	3	5	5	4	4	4	107	71%

Fig. 1 University ranking for global health participation in a technology-enabled diagnostic system

Shortage of Healthcare Workers. The shortage of healthcare workers has been well documented by the WHO and other organizations. The health worker shortage is particularly apparent in specialties such as pediatrics and oncology which are already in a critical shortage. The shortage of healthcare workers is expected to become exacerbated over the next 10 years [14,15].

Governance Challenges. Even in countries such as China that have clear, logical, written policy objectives (such as *Healthy China 2030*, co-authored by the WHO and World Bank), the day-to-day strategies to meet these objectives are not yet completely clear. The intention of the government is clear and applauded by international organizations, but the implementation is difficult as the country's leaders seek to further define tactical methods to deploy to their commitment. China has made very significant progress when compared to other developing nations in assessing their health challenges and establishing objectives [16,17].

In many places, there remains no clear path to achieve improvements. Often in these cases the authority to make particular improvements is not clear, especially as it related to defining the role between the government and the private parties providing services. For example, Livewell/Viva Afya clinics in east Africa are run as for-profit clinics but are deliberately tied into the national health system. They provide primary care in much of the country but still operate independently, albeit altruistically [18].

Governments, however, cannot do everything. Success in global health requires new thinking and innovation. Such innovation is typically provided by for-profit entities. Governments are however better positioned to provide the necessary oversight, regulation, and direct services. Governments have not been successful in many cases in making doctors available in many locations because these professionals may simply choose not to be deployed to serve in certain places.

Poor Distinction Between Public and Private Roles. Government mandates improvements but often lacks certain critical-to-function resources. The deployment of needed resources is not always something government can merely "mandate." Much of the necessary innovations required to meet certain challenges come from private industries [19].

Governments must balance the legitimate profit motive of the innovators against the widest public good. This is true in global health just as it is in other areas of public good, such as in the reduction of carbon emissions, and other global challenges [20,21]. The Livewell/Viva Afya clinics mentioned above exemplifies this as the health authorities have given these entities room to operate on a for-profit basis in exchange for the beneficial services they provide, which the government had not been able to provide due to resource limitations [18].

Poor Coordination of Participating Parties. The sustainable development healthcare goals are clear. However, because so many varied service providers (private, NGO, and governmental) take on so many highly specific tasks, there are great duplications of effort, general chaos, and a lack of consistent central data and reporting [22].

In most cases, no national reporting mechanisms are required by governments from the NGOs that are engaged in providing healthcare services. Many countries have no mechanisms to assess or manage reports even if they were to be created [23]. Beyond this, NGOs are often mandated to deal with specific disease conditions such as "polio patients" or "AIDS orphans" based on their charter at their inception and on the expectations of their donors. There is an inherent chaos in the situation simply due to the wide variety of parties engaged in healthcare services. This is exacerbated in part because, while these entities may operate under the radar of government oversight, such governments are nonetheless glad that the services are being performed charitably. However, it makes for a situation where sometimes the left hand does not know what the right hand is doing. The large number of interrelated international, national, NGO, and private charities engaged in the provision of global health in the neediest areas has the side-effect of chaos [24].

Complex Disease Factors and Comorbidities. Many charities and causes are targeted at underdiagnosed diseases. Some of these deploy specific tools to provide diagnosis. However, the situations in which they provide these diagnoses may not enable them to have a full complement of diagnostic tools available. As a result, they may diagnose a specific condition without the resources to correctly diagnose underlying causes or conditions due to multi-vector disease factors or comorbidities. For example, the PEEK VISION device may diagnose Glaucoma, but practitioners may not be able to measure persistently high blood pressure which may be the root cause [25]. Therefore, it is important that diagnostic devices become embedded in a system that can provide a more complete diagnosis, one that creates a medical record from each image or patient consultation. This medical record must become available for professional review, one that contains tests and records of interrelated symptoms, comorbidities, and even contraindications.

Public Distrust. The Wellcome Global Monitor surveyed 140,000 persons worldwide seeking to evaluate the level of trust and distrust people have in healthcare workers (specifically, doctors and nurses) and healthcare systems. The results showed that people trust doctors and nurses for knowledge more than the systems and companies they are connected with [26].

Combining this diffuse and complex public trust outcome with the shortage of qualified doctors in underserved regions, it is expected that there will be difficulties in obtaining cooperation from persons who need services. This is amplified, by very public failures of vaccines; for example, the Dengvaxia failures in the Philippines, which created significant changes in public confidence across the region [27].

Fear of Epidemiological Testing. It has been well documented in epidemiological research that persons avoid testing out of fear that a positive disease confirmation would create stigmatization within their communities, work places, or families [28–30]. They may suspect that they have a disease but may avoid testing because there is no perceived personal benefit to them. They may understand the purposes for testing requirements by the health system or health authorities, but this may go against their personal interests. As a result, many people avoid testing. Systems attempting to make a significant impact in global health must recognize these factors and have features, characteristics, and built-in mechanisms to deal with them.

Proposed Solution

We propose a technology-enabled healthcare system that initially focuses on providing diagnostics via:

(a) near ubiquitous wireless/mobile networks;
(b) using cloud based artificial intelligence routines for patient evaluation/diagnosis;
(c) information technology resources for creation of electronic medical records based on national identity cards, maintenance and sharing of medical grade data captures (imaging, sound recordings, blood panels—see Appendix A for a complete list of available technologies);
(d) medical devices currently available to provide data points for intelligent system evaluation. The authors have identified relatively mature devices with multiple data vectors. (see Appendix A)

The design and development of such a system is currently feasible with over 200 component technologies. The system can create new medical records, perform physical examinations, and a large number of additional diagnostics tests. The system will also provide a likely diagnosis, and could perhaps prescribe treatments or other next steps.

The basic concept is to prioritize diagnosis. The availability of a robust, data-based diagnostic system will be seen in underserved areas as a significant benefit by the population it serves. After providing diagnosis, the system will influence patients to take advantage of the system for treatment services as in Fig. 2.

General System Description. A system which is likely to overcome the *Problems Affecting Global Health Progress* listed in the Problems Affecting Global Health Progress Today section shall have the following minimum characteristics:

(1) Sufficient diagnostic capability such that the reputation among the target clients is one of reliability, capability, and accuracy. The system must perform at its outset with sufficient functionality to meet an acceptable threshold of correct diagnostic functions to meet or exceed the expectations of target clients;
(2) It must create an electronic medical record beginning with images of the patient national identity cards, and capable of capturing and maintaining large amounts of data, images, test results, and the like, accessible to remotely located experts;
(3) Each medical system event must be captured as a medical record;
(4) Each diagnostic device in the system must be capable of providing data which is compliant in a form required by the IT system. Each such device must be fail-safe, self-validating, self-calibrating, operator independent, confirming when a valid test has occurred with minimal opportunities for false positives or false negatives, and create a unique, patient-specific/event-specific record;
(5) The system must be intuitive, easy to operate and graphically driven. It must be reduced in complexity such that it is usable by the lowest level of healthcare workers while not being too simplistic for highly trained clinicians. It must be clinician-specific based on individual users, self-teaching, providing learning and growth to users at varying levels of competency;
(6) The system must generate graphically clear tutorials such that operators of limited training can capture validated records of physical observations and measurements;
(7) The system database structure will inherently be tailored to each language in which it operates. This need and structural algorithms are already well understood in the structures of AI diagnostic systems in development;
(8) The system would deploy connectivity, access to AI, transfer of images and medical records to the cloud, input data, provide questions and instructions, and perform other services via mobile devices (mobile phone, iPad, PC, etc.).

In addition, based on resource limitations in various governments identified in the problems above, it is our proposal the system herein described must be a collaborative system with for-profit and nonprofit entities creating and maintaining such a system.

How the Proposed System Will Address Global Health Problems

The system proposed in the General System Description section would help address the Problems Affecting Global Health Progress directly:

How This System Addresses the Lack of Resources in Poor Countries. The proposed system (AI, IT, Wireless, with named Diagnostic Devices) can feasibly be expected to provide an initial diagnosis at a remarkably low cost, likely several U.S. dollars per service. We assert that any automated diagnostic system that is primarily based on artificial intelligence, is of inherently high volume [31]. That is, through automated diagnosis via an intelligent system and low-cost consumables attached to diagnostic devices, the proposed system can achieve a cost per diagnosis at the clinic level that would likely be acceptable to most government entities. Although the availability of diagnosis would grow significantly, since the services would mostly be performed in low cost settings, the total cost to the health system would be offset by some incremental reductions in services in higher cost settings. Regardless, in many of these countries, the promise to make additional services available to all people already exists and the social cost in terms of stability and/or favorable government opinion rating is an important offsetting factor.

How This System Will Address Funding Priority Issues. The envisioned system is a public–private partnership, with financial resources contributed mainly by the private partners. The potential of offering diagnostics to a global market that is half the world's population is a compelling incentive. A country like China with 600 million underserved persons could be the initial market for the system and in this case, revenues at $1 cost per diagnosis could over time recoup money invested. Participation of the private sector would also remove the financial barriers to project implementation for governments.

How This System Addresses the Issue of the Lack of Healthcare Worker Accessibility. One of the important advantages of the proposed system is its potential to immediately begin to provide health services in regions experiencing healthcare worker shortages.

The "Doc in a box" concept that usually describes telemedicine systems applies here. The system provides diagnostic services and may also prescribe or suggest treatments for the majority of presenting conditions.

How This System Addresses the Specific Governance Challenges. By creating a public–private collaboration, with clear goals, central decision-making, and centralized services, the

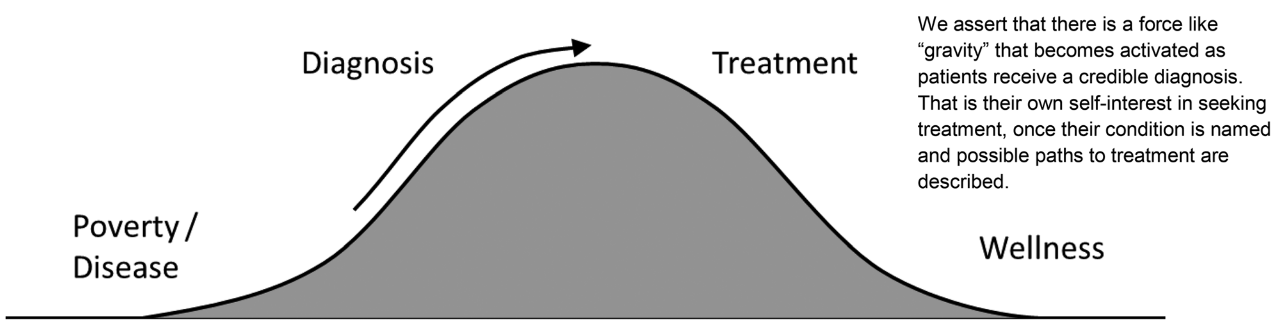

Fig. 2 How prioritizing diagnosis makes providing other services easier

system has a chance, once approved, to overcome challenges of governance by having a simple, transparent mechanism of services.

How This System Helps Delineate Public and Private Roles. The proposed system creates a clear definition of roles for public and private partners.

Due to the depth of diagnostic capabilities, the system has broad reach across roles currently being filled by a wide variety of organizations. In some cases, if the system described here is successful, it would replace the need for some existing services provided by some NGO's.

How This System Addresses the Improvements in the Coordination of Participating Parties. The proposed system would provide diagnostic services to all participants, subject to approval of the governmental agencies and departments of health.

How This System Addresses the Complex Disease Factors and Comorbidities. The system would be the first mechanism on the ground in underdeveloped areas to make a true multivector, multimorbidity diagnosis available to clients.

How This System Addresses the Problem of Public Distrust. The key to establishing public trust in such a system is the establishment of sufficient diagnostic capabilities such that a strong, positive reputation of the system's capabilities develop in remote areas by word of mouth, on social media, via mobile phone text, and other communication channels common in these underserved areas. The proposed system has robust diagnostic capabilities to win that trust from the public.

How This System Addresses the Fear of Epidemiological Testing. On the question of increasing voluntary epidemiological testing, the situation changes in the context we propose. Patients become less fearful of these tests when their own symptoms drive them to seek care in the first place. They are seeking the health services to help them understand the cause of the symptoms they are experiencing, under the assumption that the system is capable of not only a diagnosis, but of recommending treatments, some of which may be available locally, once diagnosis is confirmed. For example, the WHO Infectious Disease Target Testing List (shown on Appendix B) lists 37 communicable diseases. In fact, many of the diseases listed on the WHO Infectious Disease Target Testing List can be treated locally (in small clinics, upon confirmed diagnosis) because specific and highly effective drugs have been developed for these conditions. In cases where local treatment is not appropriate, or where local clinics cannot manage the use of certain drugs due to storage requirements or other limiting conditions, arrangements can be made to otherwise serve these patients.

Conclusions

We have identified technologies, suppliers, capabilities, and methods of integration such that a system can be built that would provide low-cost, highly reliable diagnostics in underserved regions. This system overcomes many but not all of the obstacles to providing primary care in low-resource settings. Although the cost for construction of the complete system is relatively high, it is small compared with the potential annual revenues available, even in increments from patients or health-systems.

Additional development of these concepts, the identification and evaluation of specific technologies, suppliers, medical diagnostic intelligence engines, and the like are the subject of a Feasibility Study Plan by the authors.

In summary, we are urging collaboration among world agencies engaged in global health to participate in the creation of vastly improved diagnostic systems for underserved regions.

Appendix A

Data Inputs to AI we have identified that appear to be compliant to the standards in this document, capable of being captured in a self-validating, self-calibrating, uniquely identified in a device and connected to AI systems via wireless:

(1) Collected Patient Biometric Data, general information, complaints
(2) Vital Signs:
  2.1. Blood pressure;
  2.2. Heart rate;
  2.3. Respiratory rate;
  2.4. Temperature.
(3) Family history
(4) Visual Exam, observations:
  4.1. Head;
  4.2. Eyes;
  4.3. Chest;
  4.4. Abdomen;
  4.5. Musculoskeletal system, such as hands and wrists;
  4.6. Nervous system functions, such as speech and walking.
(5) Physical Exam:
  5.1. Touching, or "palpating," parts of the body (like the abdomen) to feel for abnormalities;
  5.2. Checking skin, hair, and nails;
  5.3. Possibly examining the genitalia and rectum;
  5.4. Testing motor functions and reflexes.
(6) Blood panels: 7 panels (CMP, RFP, BMP, ELEC, HFPA, LPP, AHP); 253 reported vectors
(7) Urine panels: 64 reported vectors
(8) Stool panels: 4 reported vectors
(9) Gastric fluid panels: 4 reported vectors
(10) CSF panels: 14 reported vectors
(11) Audiometry/Tympanometry: data input from: 4 complete test devices have been identified, one of which has U.S. FDA approval
(12) Auscultation: AI to capture 77 different Auscultations for heart and lungs
(13) Replace Barium X-ray Studies: replace via "PillCam" screening
(14) Blood pressure measurement: new BP devices have been identified, one of which is being clinically evaluated by the WHO in several countries
(15) Blood tests, specific blood/discrete protein markers for a variety of diagnostic confirmations
(16) Replacement for Bone Marrow Aspiration: replace procedure with blood marker tests (see list based on alternative blood marker tests for highest order disease conditions)
(17) Bronchoscopy: images from several low-cost bronchoscope devices currently under development
(18) Replacement tests for Amniocentesis/Chorionic villus sampling/Chromosomal analysis (fetal): tests for cell free DNA in maternal blood
(19) Replacement for Colonoscopy/Sigmoidoscopy: "pill camera" device images from several new device manufacturers with AI capabilities
(20) Replacement for Colposcopy: (possibly Papanicolaou (Pap) test): several highly functioning devices have been identified which are teamed with advanced AI diagnostic systems, and which are less personally intrusive, a barrier in some regions to convenient testing
(21) Replacement for Cone biopsy (alternate: Loop Electrocautery Excision Procedure [LEEP]): Cone-biopsy may be potentially replaced with tests for several bio-markers candidates in urine or blood serum, EGFR; ErbB, HER and HER2 proteins (early research)
(22) Culture organism/WHO epidemiology priority tests: tests and methods have been identified for antibody/antigen reagent tests and confirmatory test reader

(23) Dual energy X-ray absorptiometry (DEXA): new ultrasound bone density sonometer tests have been identified with FDA approval, combined with bone reabsorption tests such as the blood deoxypyridinoline (DPD), urine Pyrilinks-D, blood carboxy-terminal (CTX), and urine amino-terminal (NTX) telopeptides (type 1 collagen)
(24) Echocardiography/Stress testing: Smart ultrasonic devices can be translated to perform Transthoracic Echocardiograms (TTE). At least one highly functional AI reading system is available
(25) Mammography: a technology has been identified, requiring additional translational research, that can provide small device and smart AI reading of cross-linked imaging data
(26) Nerve Conduction Study/Nerve Velocity Study (NCS/NVS): simple devices have been identified with AI support
(27) Ophthalmoscopy: four new methods/devices have been identified (including AI routines) to diagnose many common eye conditions
(28) Paracentesis: via discrete protein detection in blood
(29) Pulmonary Function Tests (PFT's)/Spirometry: test identified that perform 23 test vectors (complete); Three other candidate test devices have been identified
(30) Reflex Tests/Pupillary Reflex Test: system tutorials; Pupillary reflex new AI
(31) Replacement for Spinal tap procedures (lumbar puncture): we are proposing to replace spinal tap tests with tests for specific blood biomarkers based on specific test purpose/prediagnosis indications; several such tests have been identified
(32) Ultrasonography: we have identified new AI guided routines for high quality image capture
(33) X-ray (General, Injury Assessment): new small, portable, smart devices

For obvious reasons, large imaging devices are not available for small clinics. Similarly, tests requiring high rated clean rooms.

Appendix B

WHO Infectious Disease Target List:
Class A:

(1) Plague
(2) Cholera

Class B:

(3) SARS
(4) AIDS
(5) Viral Hepatitis
(6) Poliomyelitis
(7) Human Highly Pathogenic Avian Influenza (HPAI)
(8) H1N1
(9) Epidemic Hemorrhagic Fever with Renal Syndrome (EHFRS)
(10) Rabies
(11) Epidemic Encephalitis B
(12) Dengue Fever
(13) Anthrax
(14) Bacillary and Amebic Dysentery
(15) Pulmonary Tuberculosis
(16) Typhoid and Paratyphoid
(17) Epidemic Cerebrospinal Meningitis
(18) Pertussis
(19) Diphtheria
(20) Tetanus Neonatorum
(21) Scarlet Fever
(22) Brucellosis
(23) Gonorrhea
(24) Syphilis
(25) Syphilis, Leptospirosis and Schistosomiasis

Class C:

(26) Influenza
(27) Epidemic Parotitis
(28) Rubella
(29) Acute Hemorrhagic Conjunctivitis (AHC)
(30) Leprosy
(31) Epidemic and Endemic Typhus
(32) Kala-azar
(33) Echinococcosis
(34) Filariasis
(35) Infectious diarrhea other than cholera
(36) Bacillary and amebic dysentery
(37) Hand, Foot and Mouth Diseases (HFMD)

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